# PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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# PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

| | |
|---|---|
| Date of mailing *(day/month/year)* | 15.10.2004 |
| Applicant's or agent's file reference<br>JR/JPH/P8022WO | **IMPORTANT NOTIFICATION** |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/GB 03/02948 | 08.07.2003 | 09.07.2002 |

Applicant
BARTS AND THE LONDON NHS TRUST ET AL.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

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PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference JR/JPH/P8022WO | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|---|---|
| International application No. PCT/GB 03/02948 | International filing date *(day/month/year)* 08.07.2003 | Priority date *(day/month/year)* 09.07.2002 |
| International Patent Classification (IPC) or both national classification and IPC A61B18/18 | | |
| Applicant BARTS AND THE LONDON NHS TRUST ET AL. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 09.02.2004 | 15.10.2004 |
| Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016 | Authorized Officer Mayer-Martenson, E Telephone No. +31 70 340-4401 |

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/02948

## I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

**Description, Pages**

1-8 as originally filed

**Claims, Numbers**

1-11 received on 14.07.2004 with letter of 14.07.2004

**Drawings, Sheets**

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   *(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 9-11

   because:

   ☒ the said international application, or the said claims Nos. 9-11 relate to the following subject matter which does not require an international preliminary examination (specify):

   **see separate sheet**

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 9-11

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 1-8 |
| | No: | Claims | |
| Inventive step (IS) | Yes: | Claims | |
| | No: | Claims | 1-8 |
| Industrial applicability (IA) | Yes: | Claims | 1-8 |
| | No: | Claims | |

2. Citations and explanations

see separate sheet

**Cited Documents**
Reference is made to the following documents:

D1: WO 99 07315 A (LUND INSTR AB ;BOLMSJOE MAGNUS (SE)) 18 February 1999 (1999-02-18)
D2: WO 01 98764 A (FENN ALAN J ;CELSION CORP (US); MON JOHN (US)) 27 December 2001 (2001-12-27)
D3: US-A-5 129 396 (WALINSKY PAUL ET AL) 14 July 1992 (1992-07-14)

**Re Item III**
**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**
Method claims 9-11 define methods for treatment of the human or animal body by therapy or surgery practised on the human or animal body. Therefore no search has been performed for the subject matter of these claims (see Article 17 (2) PCT and Rule 39.1.(iv) PCT) and no preliminary international examination is required for the subject-matter of these method claims (see Article 34 (4) (a) (I) PCT and Rule 67.1 (iv) PCT).

**Re Item V**
**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**
V.1 The present application does not meet the requirements of PCT Article 33(3), because the subject matter of independent claim 1 does not appear to involve an inventive step as defined by the PCT regulations.

Document D1, which is considered to represent the most relevant state of the art, discloses
*an apparatus for heat ablation of the internal wall of a hollow organ, which apparatus comprises:*
*a catheter* (12) *having proximal and distal ends, and having at least one internal lumen;*
*a balloon* (11) *located at the distal end of the catheter and attached to said lumen;*
*whereby the balloon may be filled with a liquid from the proximal end of the catheter;*
*a supply of a liquid for filling the balloon via the said lumen;*
*a tuned microwave antenna* (10) *located in the region of the balloon for radiating microwave energy at a predetermined frequency to heat the balloon to a temperature suitable for heat ablation of the hollow organ wall tissue;*
*a waveguide for supplying microwave energy to the microwave antenna; and*
*a temperature probe* (37) *to measure the temperature of the balloon*
(cf. p.3,l.19 - p.4,l.4; fig.1)
from which the subject-matter of claim 1 differs in that:

*the apparatus comprises a former to centralize the antenna;*
*the liquid has a dielectric constant of from 41 to 63 and a conductivity of from 1.0 S/m to 1.5 S/m at said frequency and 50°C.*

The problem can be seen in a uniform energy distribution and a better matching of the liquid with the treated tissue for less heating of the waveguide.
The solution given in claim 1 cannot be considered inventive for the following reasons:
The main embodiment described in D1 is designed for treatment of the prostate. However also other forms of treatment are addressed, like for instant the treatment of the oesophagus or other tubular organs. In the embodiment shown in fig. 2 the antenna is offset (not centralized) from the container to protect the rectum. However in other treatments (like the treatment of the oesophagus or a blood vessel) the skilled person would not have to protect the rectum and therefore would position the antenna in the center of the container or balloon with a former like the one disclosed in D3 (cf. col. 4, l.29-32; fig. 1C).
Furthermore, in D1 the liquid is water or saline. Hence the values of the dielectric constant and the conductivity are slightly different. Additionally the fluid in container 11 is said to have the same characteristics as the treated prostate tissue (or other water rich tissue) for a perfect impedance match. In D2 the values for dielectric constant and conductivity at 915 MHZ of prostatic tissue are given as 50 and 1.3 S/m respectively.
Therefore the skilled person would fill the container of D1 with a liquid exhibiting these physical values to achieve a perfect impedance match and hence arrive at an apparatus according to claim 1.

**V.2 Dependent claims**

Dependent claims 2-8 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to inventive step, the reasons being as follows:

- claims 2,3: the features of these claims are disclosed in D2;
- claim 4,5: D1 also mentions treatment of the oesophagus (cf. p.1,l.14), the skilled man would therefore know the dimensions for treatment of the same;
- claim 6: D1 does not mention the use of metal and it would be clear for the skilled person that the use of a metal object in the vicinity of the antenna would influence the heating pattern;
- claims 7,8: the use of optical fiber probes for temperature measurement and power control is known in the art and hence not inventive;

Claims

1. Apparatus for heat ablation of the internal wall of a hollow organ, which apparatus comprises;
a catheter having proximal and distal ends, and having at least one internal lumen;
a balloon located at the distal end of the catheter and attached to a said lumen,
whereby the balloon may be filled with a liquid from the proximal end of the catheter;
a supply of a liquid for filling the balloon via the said lumen;
a tuned microwave antenna located in the region of the balloon for radiating microwave energy at a predetermined frequency to heat the balloon to a temperature suitable for heat ablation of the hollow organ wall tissue;
a waveguide for supplying microwave energy to the microwave antenna;
a former to centralise the antenna; and
a temperature probe to measure the temperature of the balloon;
wherein the liquid has a dielectric constant of from 41 to 63 and a conductivity of from 1.0 $Sm^{-1}$ to 1.5 $Sm^{-1}$ at said frequency and 50 °C.

2. Apparatus as claimed in claim 1 wherein the liquid has a dielectric constant of from 47 to 57 at said frequency and 50 °C.

3. Apparatus as claimed in either claim 1 or claim 2 wherein the liquid has a conductivity of from 1.1 to 1.35 $Sm^{-1}$ at said frequency and 50 °C.

4. Apparatus as claimed in any one of the preceding claims having dimensions such that it is suitable for heat ablation of the internal wall of the oesophagus of a human patient.

5. Apparatus as claimed in any one of the preceding claims wherein the balloon has a normal inflation diameter of from 16 to 22 mm.

6. Apparatus as claimed in any one of the preceding claims wherein the temperature probe and the balloon contain no metal.

7. Apparatus as claimed in claim 6, wherein the temperature probe comprises at least one optical fibre extending from the distal end to the proximal end of the tube.

8. Apparatus as claimed in any one of the preceding claims, including means for controlling the power supplied to the microwave antenna in dependence upon the temperature sensed by the temperature probe.

9. A process for heat ablation of the internal wall of a hollow organ of a patient, comprising the steps of;
providing a catheter having proximal and distal ends and having at least one internal lumen wherein a balloon is located at the distal end of the catheter and is connected to a said lumen, the balloon surrounding a tuned microwave antenna and a temperature probe and wherein a waveguide for supplying microwave energy at a predetermined frequency to the microwave antenna is connected to the microwave antenna;
inserting the distal end of the catheter into the hollow organ;
positioning the catheter such that the balloon is adjacent to the area of the hollow organ requiring heat ablation;
filling the balloon via the said lumen with a liquid having a dielectric constant of from 47 to 57 and a conductivity of from 1.0 $Sm^{-1}$ to 1.5 $Sm^{-1}$ at said frequency and 50 °C;
supplying microwave energy via the waveguide to the microwave antenna to heat the balloon.

10. A process as claimed in claim 9 comprising the further steps of;
providing a means for controlling the power supplied to the microwave antenna in dependence upon the temperature sensed by the temperature probe; and

controlling the power supplied to the microwave antenna to ensure heat ablation of the hollow organ of the patient.

11. A process as claimed in claim 9 or claim 10, wherein the hollow organ is the oesophagus.